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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/237,605	01/25/1999	RICHARD J. LAZZARA	IMPI.035-1	7280

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/237,605	LAZZARA ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16,51 and 57-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16,51 and 57-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 11-16, 51, and 60-75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology "uniform array of irregularities" or "substantially uniform array of irregularities" to described the degree to which the native oxide layer is removed or the uniformity of the roughness lacks original support and/or there is no guidance as to its affect on the metes and bounds of the claim language. Since there is no guidance in the original specification, it appears that even a bulk etched metal implant surface would be substantially uniform in roughness. Moreover, "substantially" is a broad term. *In re Nehrenberg*, 126 USPQ 383 (CCPA 1960) and see MPEP 2173.05(b) which is incorporated herein by reference. The specification fails to provide some standard for measuring that degree. Therefore, one of ordinary skill would not know what degree of roughness or native oxide layer would fall within the claim scope and what would not. The controlling case law appears to be that of *In re Mattison*, 184 USPQ 383 (CCPA 1960). It states:

> We are not persuaded by the board's reasoning that one skilled in the art would not be able to determine the scope of the claimed invention in terms

> of a specified percentage value. General guidelines are disclosed for a proper choice of the substituent Ep together with a representative number of examples. (emphasis added here)

The Board of Appeals was reversed because there were general guidelines as to what constituted a substantial increase. This is not the situation here where there are no guidelines in the specification, and the prior art does not give one a clear picture as to what constitutes a substantially uniform roughness and what does not. This is a critical and defining limitation of the claim and it must be clear as to what falls within its scope.

It is noted that the specification only uses the terminology "substantially uniform array of irregularities" to describe the resulting surface, and the Applicants' remarks suggest that removing substantially does not improve clarity; see page 8, first full paragraph of the response filed April 12, 2004. For this reasons, both "substantially uniform array of irregularities" and "uniform array of irregularities" is considered inadequately described.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 11-16, 51, and 60-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the claims is indefinite because of the ambiguity presented by the "substantially" terminology discussed in the 35 USC 112, first paragraph rejection.

Regarding claims 11-16, 51, and 60-67, the new language "without contacting said metal with non-titanium particles" appears to have two meanings, and thus, the scope is considered indefinite. In particular, it appears that his phrase means both contacting the surface with titanium particles and not contacting the surface with any particles whatsoever.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-16 and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al (the translation of Japanese patent JP3146679A2) in view of Krueger (US 4,826,434). Haruyuki discloses an acid etched titanium implant surface with recesses having average depths of 0.5 to 5 microns; see the abstract and the "Technical Field" paragraph on page 2. Haruyuki discloses making dental repair and biorepair members including bone fixation devices and artificial dental roots, but

fails to disclose implants made with threads as claimed. However, Krueger teaches that it was known to make dental implants with threaded surfaces in order to sufficiently anchor the device into the bone. Hence, it is the Examiner position that it would have been obvious to put threads on the Haruyuki dental implants in order to allow them to be securely and quickly inserted into a bone hole without sliding out therefrom.

With regard to the new limitation pertaining to the minimum consumption of metal, the Examiner asserts that this process step would not affect the final surface property, and thus, the resultant product would be the same as one where there was a more than minimum consumption of metal; see MPEP 2113, which is incorporated herein by reference thereto.

With regard to claims 12 and 57-59, the Examiner posits that since a similar type of etching process is used to form irregularities on the surface of the same material as claimed that the surface irregularities of Haruyuki would inherently be the same as those set forth in the claims; i.e. cone-shaped and/or spaced about the prescribed distance.

Furthermore, upon review of Exhibit 1 and Exhibit B, Comparative Example 2 of the Dr. Gubbi declaration filed June 30, 2003, the Examiner concluded that the prior art treatments do result in cone-shaped elements; see the micrographs thereof and compare to the micrographs of Exhibit A. Thus, this evidence is used as evidence that cone-shaped elements are inherently present on the surface of Haruyuki.

Claims 51 and 60-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haruyuki et al (the translation of Japanese patent JP3146679A2) in view of Niznick

(US 5,571,017). Haruyuki meets the claim language as explained *supra* but fails to teach both a roughened region and an unroughened or other region, the tapered section, and the self-tapping section as required by the claims. However, Niznick teaches that it was known in the art to have different regions of roughness where the roughened portion begins below the top surface, a tapered section, and a self-tapping feature; see the abstract, Figure 1, column 2, lines 1-12, column 2, line 66 to column 3, line 24, column 4, lines 22-37, column 4, line 56 to column 5, line 6, and column 7, lines 9-24. Hence, it is the Examiner's position that it would have been obvious to have a smoother head portion in the Haruyuki invention for the same reasons that Niznick has the same.

Response to Arguments

Applicant's arguments filed April 12, 2004 have been considered but they are not persuasive.

In response to the argument that the Section 112, first paragraph rejection should be withdrawn, it is noted that the specification only uses the terminology "substantially uniform array of irregularities" to describe the resulting surface, and the Applicants' remarks suggest that removing substantially does not improve clarity; see page 8, first full paragraph of the response filed April 12, 2004. For this reasons, both "substantially uniform array of irregularities" and "uniform array of irregularities" is considered inadequately described. This is due to the fact that the case law cited in the rejection suggests a broad interpretation should be used, but the Applicants' arguments and specification suggest a narrow interpretation for this language. Therefore, the Examiner

suggest deleting the language both of these phrases entirely so that there is no confusion in this regard.

In response to the Applicants' argument that the "substantially" objection should be withdrawn, it is the Examiner's position that since there is a lack of guidance in this regard, it would not be proper to withdraw the rejection. This is due to the fact that the case law is relatively clear as to what is required and the present disclosure falls short of that standard.

The Applicants argue that Figure 1 of the present specification shows a substantially uniform texture while Figure 3 does not. However, the line between the two has not been made clear. It is not clear whether device with a smaller area than that shown in Figure 3 would constitute a substantially uniform texture.

In response to the arguments directed against the Haruyuki rejection that Haruyuki uses acid treatment to smoothen the surface not roughen it as alleged Krueger teaches, the Examiner asserts that Haruyuki does not teach smoothening the surface. Rather, Haruyuki explains that there is an optimum surface characteristic to obtain for cell adhesion and ongrowth. Acid treatment with a too strong acid (over 6% HF) leads to too large of pores sizes while a too weak acid (under 1% HF) leads to too small of pores sizes; see page 4, left column of the translation. Smoothness is not explicitly discussed. Rather, only rough edges and pores sizes are discussed. Furthermore, the fact that Harayuki wants to optimize pores size and depth to promote cell attachment does not teach away from Krueger, but instead teaches a way of achieving what both references desire: cell attachment and ongrowth.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738